Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act

1. <u>IDENTIFICATION OF THE INFORMATION COLLECTION</u>

(a) Title and Number of the Information Collection

Title: Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports

EPA ICR No. 1011.05

OMB Control No. 2070-0070

(b) Short Characterization

This request for renewal of an approved information collection is made in order to satisfy basic information requirements of the Toxic Substances Control Act (TSCA). Section 8(b) of TSCA requires EPA to compile and maintain, via periodic inquiry, the Inventory of Chemical Substances in Commerce. This inventory, commonly referred to as the TSCA Inventory, is a listing of chemical substances manufactured, imported and processed for commercial purposes in the United States. The Office of Prevention, Pesticides and Toxics Substances (OPPTS) updates this inventory every four years by collecting volume and manufacturing site information on about 8,900 of the more than 75,000 chemicals on the TSCA Inventory. The TSCA Inventory Update Rule requires the submission of information on mostly organic chemicals produced or imported in volumes greater than 10,000 pounds per year.

The Information Management Division of OPPTS' Office of Pollution Prevention and Toxics (OPPT) will collect this information on chemical substances and will use it to update the TSCA Inventory. Individual plant or factory sites producing or importing chemicals will submit the required information. The information will be stored and used in both hard-copy and electronic forms for reference by EPA staff and others.

2. NEED FOR AND USE OF THE COLLECTION

(a) Need/Authority for the Collection

Under TSCA, EPA is required to identify, assess and control risks of injury to human health and the environment posed by commercial chemicals. Under TSCA section 8(b), EPA is required to compile and keep current a complete list of chemical substances manufactured or processed in the United States. Under TSCA section 8(a) the Administrator shall promulgate rules to provide for the maintenance and collection of records from manufacturers, importers and processors of commercial chemicals. The Inventory Update Rule (IUR) is codified at 40 CFR 710. Copies of the relevant

sections of TSCA and of the Code of Federal Regulations are attached (see Attachments 1 and 2).

(b) Practical Utility/Users of the Data

The Inventory Update Rule information collection will enable EPA to procure basic information on TSCA commercial chemicals, including current production volume and site-related data. This information is necessary because it is the only mechanism through which EPA's need for basic information on the chemical industry can be fully and effectively satisfied. The information collected is utilized in the following ways:

- 1. Production Volume: This information is utilized as a tool for chemical screening, testing/review priority setting and exposure estimation required by the Interagency Testing Committee (ITC) under TSCA section 4, for EPA monitoring activities of newly manufactured substances that have completed PMN review under TSCA section 5(a), to support the development of TSCA regulations under section 6, and to measure potential of human and environmental exposure under TSCA section 8(e).
- 2. Plant Site Information: These data are utilized for estimating total human and environmental exposure and to identify specific plant site owners so as to be able to communicate with them. As such, this information is sought for purposes related to regulatory activities under TSCA sections 4, 6 and 8.
- 3. Site-limited Status Information: This information is utilized by EPA in chemical screening, priority setting, and exposure estimation for various TSCA purposes, especially for TSCA sections 4, 6 and 8. A site-limited substance is presumed to have lower exposure potential because it is not distributed outside the manufacturing plant for commercial purposes.

Information secured through the Inventory Update Rule collections is increasingly used by a wide variety of governmental and non-governmental users. Consistent with Congress's intent that TSCA data be used to facilitate any government public health and environment efforts, IUR data have been used by EPA's Office of Water, Office of Solid Waste and Emergency Response, and Office of Air and Radiation to identify and characterize particular chemical substances. Non-confidential IUR data are incorporated into a number of databases and products maintained by organizations including Right-To-Know-Net and INFORM¹. IUR data were used to identify chemicals of particular concern for the National Institutes of Health. Non-confidential IUR data were also released to selected states to help them identify facilities manufacturing suspected endocrine disruptors.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

(a) Non-Duplication

¹ INFORM is a nonprofit environmental research organization.

EPA has examined data sources other than the Inventory Data Base and the Updated Inventory Data Base to determine whether these sources could provide the information that the Agency needs under TSCA. EPA determined no source, either individually or utilized in conjunction with others, could be utilized as a substitute for the Updated Inventory Data Base.

(b) Public Notice Required Prior to ICR Submission to OMB

In proposing to renew this ICR, EPA provided a 60-day public notice and comment period that ended on June 4, 2001 (66 FR 17704, April 3, 2001; see Attachment 6). EPA received numerous comments, most of which were essentially identical (see Attachment 7). The comments were taken into consideration during the preparation of this ICR and are addressed in Section 6 of this document.

(c) Consultations

Prior to proposing the Inventory Update Rule, EPA consulted with the following agencies/groups: (1) the Consumer Product Safety Commission, (2) the Department of Health and Human Services, National Toxicology Program, (3) the National Library of Medicine, (4) the Interagency Testing Committee, (5) the National Institute for Occupational Safety and Health, and (6) the Organization of Chemical and Atomic Workers.

All of the agencies/groups contacted supported EPA's proposed efforts to update the Inventory Data Base. Three of these groups actively participated in the EPA Workgroup that was responsible for determining the scope of the update and addressing a series of regulatory and technical issues concerning this information collection. EPA has continually consulted with industry during and following the 1986, 1990, 1994, and 1998 reporting periods. Companies have provided suggestions concerning improvements in implementation of the rule.

Additionally, EPA conducted a survey (under Office of Management and Budget Control #2070-0034)² to assess the potential burden associated with amendments to the IUR. These amendments are currently under development. The survey was distributed to a stratified subset of previous IUR reporters selected from the Chemical Use System (CUS) database.³ Respondents were asked to estimate the burden associated with collecting various data for each of three labor categories: clerical, technical, and managerial. Questions included not only the burden associated with the new requirements, but also the burden associated with the current reporting requirements. The results of the survey provided the basis for revising the burden associated with the IUR in the analysis provided in this

²The survey was conducted for EPA by ICF Incorporated, an EPA contractor supporting TSCA initiatives. This work was performed under EPA Contract No. 68-02-0064.

³EPA maintains the Chemical Update System (CUS) Database to track IUR information.

supporting statement.

(d) Effects of Less Frequent Collection

The Agency needs to be able to make accurate chemical regulatory decisions in a timely and cost effective manner, especially since alternative data sources do not exist for these data. The effect of less frequent collection of these data is that the Agency's ability to understand the chemical industry and monitor the production levels of chemicals produced or imported in the United States would be significantly diminished. Based on IUR data, the statistics show that chemical industry product lines and manufacturing in the United States change rapidly from one reporting period to the next. This demonstrates that the IUR exercise needs to be undertaken at least every four years in order for the Agency to fulfill its mandate to keep the TSCA Inventory current under Section 8(b) of TSCA.

(e) General Guidelines

This collection does not exceed any of the Paperwork Reduction Act guidelines at 5 CFR 1320.6.

(f) Confidentiality

Respondents may claim information submitted to EPA under this rule as confidential if such information would reveal the submitters' trade secrets or proprietary information as defined by TSCA section 14 and existing TSCA regulations. EPA has long-established procedures for handling, storing, processing and disposing of TSCA confidential information. Transfers of this information to other governmental agencies can only be accomplished if the other agency agrees to adhere to all TSCA confidentiality provisions.

(g) Sensitive Questions

This collection does not include questions of a sensitive nature.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

(a) Respondents/SIC and NAICS Codes

The regulated community consists of persons manufacturing or importing chemicals listed on the TSCA Inventory and regulated under TSCA Section 8. In general, the industry segments that compose the regulated community for this information collection are those that produce or import organic chemicals. Using Standard Industrial Classification (SIC) codes such persons are typically classified under *Chemical Allied Products Manufacturers* (SIC 28) and *Petroleum Refining and Related Industries* (SIC 29). Using North American Industry Classification System (NAICS) codes, these persons are typically classified under *Chemical Manufacturing* (NAICS 325) and *Petroleum and*

Coal Product Manufacturing (NAICS 324).

(b) Information Requested

In the following paragraph EPA describes the paperwork requirements associated with the TSCA Section 8(b) Inventory Data base, Production and Site Reports.

(i) Data Items

Using Form U (*EPA Form* #7740-8, see Attachment 3), respondents report on (1) company and site address, (2) Dun and Bradstreet number for company, (3) each chemical identity, (4) each chemical activity, either manufacturing or importing, and (5) production volume for the reporting year for each chemical. Respondents are required to retain records supporting their submission for a period of four years. There are no changes to the data items since the last ICR renewal.

(ii) Respondent Activities

To complete the collection, the respondent would:

- A) Determine compliance;
- B) Become familiar with rule;
- C) Prepare and submit report; and
- D) Keep records.

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY AND INFORMATION MANAGEMENT

(a) Agency Activities

The activities routinely conducted by EPA related to the processing, analysis and storage of the information collected under this rule include the following:

- review and verify forms as they are received,
- answer respondent's questions and provide any necessary assistance,
- process submissions for inclusion in IUR database,
- review requests for confidentiality in the submissions,
- maintain the database, and
- distribute the data.

(b) Collection Methodology and Management

The information collection activity under this rule includes an initial reporting period (which took place during 1986) and subsequent reporting periods (1990, 1994, and 1998). For each reporting

period, all manufacturers (including importers), except for those defined as "small manufacturers," are required to submit on every substance required under this rule. After the initial reporting period, subsequent reports are required every four years, with the next reporting period taking place in 2002. The substantive information requirements of the 2002 reporting period are identical to those of the 1998 period, which were identical to those of the previous reporting periods. The only changes made since 1998 have been for the purpose of facilitating reporting and information processing: allowing electronic reporting and making the reporting form simpler to complete. The collection instruments and measures employed have been effective in the past four information collection efforts.

(i) Collection Methodology

Respondents will be able to obtain the reporting form in a variety of ways, as follows:

- EPA will mail a reporting package to companies who reported during the previous reporting cycle.
- Respondents will be able to obtain reporting packages from the TSCA Hotline.
- Respondents will be able to download the reporting form from the Internet.

In submitting the information associated with this data collection, respondents will be able to choose either a mail-in form or an electronic form (on a disk). EPA has considered electronic submissions using the Internet, but at this time is unable to guarantee security of CBI submitted in that manner. Respondents are encouraged to use electronic submission whenever possible. About half of the respondents reported electronically during the 1998 collection. This is expected to increase to 75% for the 2002 collection. Increased use of electronic submissions have increased the quality of the IUR database by reducing errors due to manually adding information to the database.

To aid persons subject to the IUR information collection, OPPT has set up a TSCA Hotline that provides information regarding the TSCA Inventory reporting, as well as other regulatory information. When Hotline staff are unable to answer questions regarding the IUR, the questions are referred to EPA's Information Management Division (IMD) staff for appropriate resolution. Other Divisions within OPPT will be used as necessary. IMD is also responsible for providing access to the data.

Companies reporting to the IUR will be encouraged to report electronically on magnetic media or via the Internet using EPA-developed software. Initial data receipt and processing activities (data entry, quality assurance, CBI claim reviews, etc.) will be expedited by the receipt of the data electronically. EPA expects that receiving the additional information required under the rule will have a negligible impact on its front end processing activities. Optional Character Recognition (OCR) technology will be employed to facilitate processing of reports received in hard copy.

(ii) Data Management

This section describes the Agency tasks required for efficiently processing submissions under

the IUR. The tasks for which the Agency is responsible are presented under four main categories: database systems development, guidance document development, Form U processing, and additional tasks. The task descriptions presented below generally do not change.

Information will be used to update and augment the CUS and Chemicals in Commerce Information System (CICIS) databases. These databases will then be available to EPA technical reviewers for export into their various analytical modeling systems and databases. The IUR database will also be available for quick screening and other direct uses. Non-CBI information will be publically available.

- <u>Database Systems Development and Maintenance</u> -- The Agency is responsible for having adequate information systems in place to support the CUS that serves as the primary data storage medium for IUR collections. File servers with appropriate backup are used to contain the IUR databases. In addition, IUR data are tracked via the correspondence tracking system utilized by the Confidential Business Information Tracking System (CBITS) located within the Confidential Business Information Center (CBIC).
- <u>Guidance Document Development</u> -- The Agency is responsible for developing guidance for the IUR to assist reporters in complying with IUR requirements. The guidance documents usually are developed by a contractor with oversight by Agency personnel.
- Form U Processing -- The Agency is responsible for handling processing of IUR submissions. This includes developing standard operating procedures and documentation for all stages in the IUR document life cycle, document receipt and tracking, data input, quality control, file and database maintenance, information security, CBI aggregation policy, data dissemination, and staff training.
- <u>Additional Activities</u> -- The Agency publishes and prints the IUR form and other miscellaneous materials. In addition, the Agency is responsible for providing the TSCA Hotline with standardized responses for frequently asked questions; preparing mailings, mailing lists, and labels; and developing outgoing information materials.

(c) Small Entity Flexibility

Small manufacturers, including importers, as defined in the rule, are generally not subject to any of the reporting or recordkeeping requirements and are exempt. In accordance with TSCA section 8(b) (40 CFR Sections 710.29 and 710.28), the Inventory Update Rule contains a small business exemption. A manufacturer or importer is considered a small business if (1) the firm's total annual sales when combined with those of its parent company (if any) are less than \$40 million for the reporting period and (2) its total production and/or importation of the chemical substances, mixture or category, for the reporting period, does not exceed 100,000 pounds (45,000 kilograms) at an individual site

owned and controlled by the firm. Therefore, there is minimal, if any, burden on small business.

(d) Collection Schedule

The reporting period shall be from August 25 to December 23, 2002. This reporting period/schedule follows the requirements of 40 CFR Ch.1 Section 710.33(b).

Federal Register Notice May 2002

Letter to 1998 IUR mailing list June 2002

Send out IUR information package; June 2002

Information is also available on EPA's web page, www.epa.gov/opptintr

Going Public efforts: Include June 2002

articles in industry press, meetings with regulated community, and information available through the Internet.

Open period for filing 1998 August 26, 2002 - IUR information December 23, 2002

6. <u>ESTIMATING THE BURDEN AND COST OF THE COLLECTION</u>

(a) Estimating Respondent Burden

This ICR addresses an information collection effort undertaken in essentially the same form since 1986. This is the fifth in the series of inventory updates scheduled by regulation to be conducted every four years. The burden estimates for report preparation and submission were derived from a survey conducted by EPA during the spring/summer of 1996 (under Office of Management and Budget Control #2070-0034, which expired in 1998) to assess the potential burden associated with the amended IUR.⁴ The survey was distributed to previous IUR reporters selected from the CUS database. Worksheet 1 illustrates the respondents' burden of collection on a per-collection basis.

⁴Survey discussed in section 3(c) of this supporting statement.

The Agency estimates the average annual respondent burden for this information collection activity to be 21.88 hours. This burden estimate assumes that respondents will report IUR information for an average of 9 chemicals based on the information in the CUS database, with an average per chemical burden of 2.4 hours. The IUR requires reporting on a "per site" basis rather than a "per company" basis. There are no third party burdens associated with these activities.

As stated in Section 3(b) of this document, EPA received several public comments in response to the proposed renewal of this ICR. In response to these comments, EPA reviewed the burden estimates used in past updates, information provided in the comments, and information gathered during past IUR reporting periods and incorporated information from the 1996 survey conducted to evaluate amendments to the IUR. The comments, and EPA's responses, are characterized below.

Commenters continually stated that EPA estimates of burden were "wholly inaccurate and unrealistic." After analyzing the public comments, it appears that commenters are spending typically 1-3 hours per chemical (with a range of 0.1 to 41 hours per chemical). To analyze these comments, EPA combined commenter information with actual reporting data from 1998 IUR submissions. None of the commenters had provided the number of chemicals they reported on, and few provided the number of reports they submitted. Most commenters provided a total number of hours, and did not make it clear if they were talking about one site or all of their company sites. However, many were clearly comparing overall company costs (where a company has several sites) to EPA's single site estimate. EPA's previous estimate of about 1.3 hours per chemical, on average, has been increased to 2.43 hours based primarily on information developed for the Amendments to the IUR (IURA), as discussed in section 3(c) of this document. This revised estimate is consistent with the analysis based on public comments.

Commenters made it clear that different companies have different experiences. For instance, some of the commenters mentioned how difficult and time consuming it is to collect data on imported chemicals. However, the American Petroleum Institute (API) states that "less time is needed for smaller facilities, as well as sites that are subject to reporting only by virtue of importing a relatively small number of chemicals." Additionally, API states that "corporate-led coordination leads to efficiencies that lower the time required per site." This statement appears to be in opposition to other comments discussing the time needed for dissemination of information, centralized coordination of reporting, and other similar issues. EPA fully expects different companies to have different burden levels, and the estimates provided in this report denote a typical company. EPA agrees that there are companies with a far greater burden than discussed herein, as well as companies with a far lower burden.

A commenter suggested that EPA should take into account the "time necessary to identify and calculate volumes of chemical substances in mixtures." EPA estimates of burden are for average burden. Some sites and some specific substances are expected to require a greater than average burden in order to comply with the rule, just as some are expected to require a lower burden.

A commenter also indicated that time spent to investigate chemicals not being reported, time

needed to make and support a CBI claim, time to determine if a substance is on the TSCA inventory, and time to coordinate and train personnel are overlooked. EPA's "compliance determination" time is intended to account for the time needed to determine whether a company needs to report under the IUR, including whether a chemical is on the TSCA Inventory, and for which chemicals that company site would report. Time to make and support a CBI claim is incorporated into the burden estimates. It is important to note that not all respondents make CBI claims, therefore those that do may be in the "above average burden" category. Individual companies use different methods to ensure their company, including their personnel, is equipped to report under the IUR. Again, burden associated with these individual choices is included in the estimates, although the Agency recognizes that the experience can vary widely from one company to another.

Comments from API contained burden data from an API informal survey. Five of API's 400 member companies reported burden estimates of 24 hours to 481 hours per facility. Based upon the data from these five companies, API suggested 98 hours per facility as a more representative burden. EPA disagrees that results for all companies reporting under the IUR can be determined from a small sampling of a specific segment of those companies. EPA's survey, discussed previously, draws from a representative sample of past IUR respondents, and provides a better estimate of the burden associated with the collection.

(b) Estimating Respondent Cost

The wage rates for managerial, technical, and clerical skill levels were developed from information provided by the Bureau of Labor Statistics (BLS) and an analysis adopted from the *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313* (EPA, 1997). Worksheet 1 also illustrates the respondents' cost of reporting on a per-collection basis. The costs in worksheet 1 have been updated to reflect current wages rates. See Attachment 4 for a discussion of the development of rates process. Since this has been an ongoing collection, there are no capital or operations and maintenance costs associated with the current collection. The Agency assumed that any costs associated with developing a database or information management system were incurred with the first collection.

Worksheet 1: Respondent Burden and Cost Estimates, Per Respondent (Site) (2000 \$)

Activity	В	urden Hours	Total	Total	
	Manageria l @ \$95.55	Technical @ \$65.96	Clerical @ \$27.37	Hours	Costs
Compliance Determination	0.00	4.00	0.00	4.00	263.84
Rule Familiarization	2.00	2.00	0.00	4.00	323.02

Activity	В	urden Hours	Total	Total	
	Manageria l @ \$95.55	Technical @ \$65.96	Clerical @ \$27.37	Hours	Costs
Report Preparation and Submission	2.98	5.39	1.51	9.88	681.59
Recordkeeping	1.00	2.00	1.00	4.00	254.84
Total	5.98	13.39	2.51	21.88	1,523.29

A commenter stated that EPA cost estimates should include the cost to track production and importation volumes. However, companies collect this type of information for a variety of reasons, including normal business operations. EPA does not believe that costs associated with this tracking should be attributed to the IUR.

Commenters also complained that the wage rates were too low for two reasons. First, the commenters stated that EPA estimates use mostly technical staff, but "IUR reporting generally involves some time for highly paid professionals, such as corporate staff. EPA does not include labor rates for this category." This assumption on the part of commenters is incorrect. Both the managerial and technical categories include such staff. These categories represent the average of a range of staff levels, and the staff level at the top end of the technical category is the same as the top end of the managerial category (the average is different due to differences at the lower end of the categories). Second, several companies stated their actual rates, which were higher than those used in this analysis. The rates used herein represent a large cross section of companies, as described in Attachment 4. It is reasonable to expect that some individual costs would be higher and some lower than these estimates.

(c) Estimating Agency Burden and Cost

Annual costs and burden to the Agency under the IUR have been estimated by calculating the number of full-time equivalents (FTEs) required to undertake certain prescribed tasks. FTEs are converted to dollars by multiplying estimated FTE yearly earnings for the appropriate staff level (GS level) by the number of FTEs for each staff level, and then summing the products. Yearly earnings have been calculated to include fringe benefits of 41 percent of the base salary and overhead costs of 17 percent of the base salary plus the fringe benefits. Additional Agency costs have been estimated based on the budget that is appropriated for the IUR (EPA, 2001).

Worksheet 2 presents the annual Agency costs of the IUR information collection without the amendments. The estimated total annualized cost incurred by the Agency is the sum of the annual operations and maintenance costs. This annualized cost is equal to about \$310,890.

Worksheet 2. Estimated Annual Agency Costs for the IUR

Task	IUR Costs (2000 \$)
Tasks Performed by Agency Personnel	
Quality Control of Data Entry	\$90,103 (1 FTE, GS-12)
Data Processing, Systems Development, and Contract Oversight and Management	\$107,147 (1 FTE, GS-13)
Subtotal	\$197,250
Extramural Tasks (contractor)	
Document Receipt and Tracking and Data Entry	\$42,642
Backup Systems Operation	\$26,651
Subtotal	\$69,293
Additional Tasks	
Publication and Printing Forms and Materials	\$1,066
Hotline	\$42,855
Mailing	\$426
Subtotal	\$44,347
Total Annual Cost	\$310,890

Note: All costs associated with FTEs include 41 percent fringe benefits and 17 percent overhead.

Sources:

Office of Personnel Management. 2000. "2000 General Schedule Locality Notes of Pay for Washington-Baltimore, DC-MD-VA-WV." http://www.opm.gov/oca/2000tbls/GSannual/html/GSDCB.HTM As obtained on May 30, 2000.

EPA. April 1997. *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313*. Regulatory Impacts Branch, Office of Pollution Prevention and Toxics.

Information Management Division. 1996. Questions for Branches within OPPT with Responsibility for IUR Data Collection, Processing, and Storage. Information Management Division, U.S. Environmental Protection Agency, Washington, DC.

EPA. August 29, 1996b. Transcribed Telephone Conversation with Ruth Heikkinen on Hotline and Mailing Costs, Office of Pollution Prevention and Toxics.

EPA. July 30, 1996a. IUR Amendments—Agency Costs Question. Memorandum from Ward Penberthy to Susan Krueger, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency.

(d) Bottom Line Burden Hours and Cost: Master Table

Previously, EPA estimated that 3,000 respondents (sites) would report under this collection. The last collection, conducted in 1998, resulted in approximately 2,700 respondents reporting. An estimate of 3,000 will be used for this renewal request. At 21.88 hours per respondent, the total burden per reporting cycle collection is estimated to be 65,640 hours. At a cost of \$1,523 per respondent, the total cost per reporting cycle collection is \$4.6 million. Since this collection occurs every four years, the total annual burden is 16,400 and the annual cost is \$1.14 million, or 5.47 hours at a cost of \$380.82 per respondent. Details are provided in Worksheets 3 and 4.

EPA estimates that Agency costs will be \$310,890 for the collection, or \$77,723 annually.

Worksheet 3: Total Estimated Burden Hours and Costs (2000 \$)

Activity	I	Burden Hou	rs		otal per pondent	Number of Respon-	Totals per Collection ¹		
	Mgr @ \$95.55	Tech @ \$65.96	Cler @ \$27.37	Hrs	\$	dents	Hrs	\$	
Inventory Update R	Inventory Update Reporting								
Compliance Determination	0.00	4.00	0.00	4.00	263.84	3000	12000	791,520	
Rule Familiarization	2.00	2.00	0.00	4.00	323.02	3000	12000	969,060	
Report Preparation and Submission	2.98	5.39	1.51	9.88	681.59	3000	29,640	2,044,770	
Recordkeeping	1.00	2.00	1.00	4.00	254.84	3000	12000	764,520	
Subtotal Per Collection	5.98	13.39	2.51	21.88	1523.29	3000	65,640	4,569,870	
Subtotal Annually ¹	1.49	3.35	0.63	5.47	380.82	3000	16,410	1,142,468	

¹ This collection occurs every four years.

Worksheet 4: Bottom Line Hours and Costs for Respondents (2000 \$)

Activity	Burden Hours			Total per Respondent		Number of Respon-	Totals	
	Mgr @ \$95.55	Tech @ \$65.96	Cler @ \$27.37	Hrs	\$	dents	Hrs	\$
Total Per Collection	5.98	13.39	2.51	21.88	1523.29	3000	65,640	4,569,870
Total Annually	1.49	3.35	0.63	5.47	380.82	3000	16,410	1,142,468

(e) Reasons for Change in Burden

EPA estimates the total public burden to be 65,640 hours, or 16,410 hours per year during the IUR reporting cycle. This is an increase of 31,140 burden hours from the 34,500 hours estimated under previous clearance for this ICR (or, an increase of 7,785 hours annually, from 8,625 hours annually). EPA conducted a survey (under Office of Management and Budget clearance #2070-0034)⁵ to assess the potential burden associated with amendments to the IUR. These amendments are currently under development. The survey was distributed to a stratified subset of previous IUR reporters selected from the Chemical Use System (CUS) database.⁶ Respondents were asked to estimate the burden associated with collecting various data for each of three labor categories: clerical, technical, and managerial. Questions included not only the burden associated with the new requirements, but also the burden associated with the current reporting requirements. The results of the survey provided the basis for revising the burden associated with the IUR in the analysis provided in this supporting statement. This increase is due to an **adjustment** made by the agency after reassessing the burden associated with complying with this regulation.

(f) Burden Statement

The total public burden for this collection of information, which is approved under OMB Control No. 2070-0070, is estimated to average 21.88 hours per response, with an estimated cost of \$1,523.29 per response. The total estimated annual burden is between 16,410 hours, with an estimated total annual cost \$1,142,468. This activity occurs only every four years, and the burden and cost vary depending on the specific chemical and company activities. According to the Paperwork Reduction Act (PRA), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install, and utilize

⁵The survey was conducted for EPA by ICF Incorporated, an EPA contractor supporting TSCA initiatives. This work was performed under EPA Contract No. 68-02-0064.

⁶EPA maintains the Chemical Update System (CUS) Database to track IUR information.

technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. In addition, the OMB control numbers for EPA's regulations, after initial display in the final rule, are listed in 40 CFR part 9.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to: Director, Collection Strategies Division, U.S. Environmental Protection Agency (Mail Code 2822), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the requested information to this address. The requested information should be submitted in accordance with the instructions accompanying the form, or as specified in the corresponding regulation.

ATTACHMENTS TO THE SUPPORTING STATEMENT

(Attachments are available as part of the electronic file for this supporting statement unless otherwise noted).

Attachment 1	Toxic Substances Control Act, Section 8 (15 USC 2607)
Attachment 2	40 CFR 710 - TSCA Inventory Update Rule
Attachment 3	Form U and Instructions (<i>EPA Form #7740-8</i>). Available electronically at http://www.epa.gov/opptintr/iur98/forms.htm .
Attachment 4	Methodology for Determination of Wage Rates
Attachment 5	Display Related to OMB Control #2070-0070 - Listing of Related Regulations in 40 CFR Part 9.1
Attachment 6	Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports; Request for Comment on Renewal of Information Collection Activities (66 FR 17704, April 3, 2001). Available electronically at http://www.epa.gov/fedrgstr/EPA-TOX/2001/April/Day-03/t8134.htm .
Attachment 7	Comments Received in Response to April 3, 2001 Notice and Request for Comment (66 FR 17704). Not available electronically.

ATTACHMENT 1

Toxic Substances Control Act Section 8

15 USC 2607

Sec. 2607. Reporting and retention of information

(a) Reports

- (1) The Administrator shall promulgate rules under which -
 - (A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and
- (B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process -
 - (i) a mixture, or
 - (ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product, shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this chapter. The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this chapter. For purposes of the compilation of the list of chemical substances required under subsection (b) of this section, the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after January 1, 1977.
- (2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:
 - (A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.
 - (B) The categories or proposed categories of use of each such substance or mixture.
 - (C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.
 - (D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.
 - (E) All existing data concerning the environmental and health effects of such substance or mixture.
 - (F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.
 - (G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such

manner or method. To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.

(3)

(A)

- (i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b) of this section.
- (ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture -
 - (I) subject to a rule proposed or promulgated under section 2603, 2604(b)(4), or 2605 of this title, or an order in effect under section 2604(e) of this title, or
 - (II) with respect to which relief has been granted pursuant to a civil action brought under section 2604 or 2606 of this title, to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).
- (B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(b) Inventory

- (1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 2604 of this title or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1) of this section. In the case of a chemical substance for which a notice is submitted in accordance with section 2604 of this title, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after January 1, 1977. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.
- (2) To the extent consistent with the purposes of this chapter, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(c) Records

Any person who manufactures, processes, or distributes in commerce any chemical substance or

mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

(d) Health and safety studies

The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator -

- (1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this chapter; and
- (2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

(e) Notice to Administrator of substantial risks

Any person who manufactures, processes, or distributes in commerce as chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

(f) "Manufacture" and "process" defined

For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

ATTACHMENT 2

40 CFR 710

- § 710.1 Scope and compliance.
- (a) This part establishes regulations governing reporting by certain persons who manufacture, import, or process chemical substances for commercial purposes under section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)). Section 8(a) authorizes the Administrator to require reporting of information necessary for administration of the Act and requires EPA to issue regulations for the purpose of compiling an inventory of chemical substances manufactured or processed for a commercial purpose, as required by section 8(b) of the Act. Following an initial reporting period, EPA published an initial inventory of chemical substances manufactured, processed or imported for commercial purposes. In accordance with section 8(b), EPA periodically amends the inventory to include new chemical substances which are manufactured or imported for a commercial purpose and reported under section 5(a)(1) of the Act. EPA also revises the categories of chemical substances and makes other amendments as appropriate.
- (b) Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under these reporting regulations. In addition, section 15(3) makes it unlawful for any person to fail to keep, and permit access to, records required by these regulations. Section 16 provides that any person who violates a provision of section 15 is liable to the United States for a civil penalty and may be criminally prosecuted. Pursuant to section 17, the Government may seek judicial relief to compel submission of section 8(a) information and to otherwise restrain any violation of section 15.

Note: As a matter of traditional Agency policy, EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting.

(c) Each person who reports under these regulations shall maintain records that document information reported under these regulations and, in accordance with the Act, permit access to, and the copying of, such records by EPA officials.

[42 FR 64572, Dec. 23, 1977, as amended at 45 FR 18375, Mar. 21, 1980; 60 FR 31921, June 19, 1995]

§ 710.2 Definitions.

In addition to the definitions in § 704.3 in this chapter, the following definitions also apply to this part:

(a) The following terms shall have the meaning contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., and the regulations issued under such Act: Cosmetic, device, drug, food, and food additive. In addition, the term food includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 et seq.; meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 et seq.; and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 et seq.

- (b) The term pesticide shall have the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq., and the regulations issued thereunder.
- (c) The following terms shall have the meaning contained in the Atomic Energy Act of 1954, 42 U.S.C. 2014 et seq., and the regulations issued thereunder: byproduct material, source material, and special nuclear material.
- (d) Act means the Toxic Substances Control Act, 15 U.S.C. 2601 et seq.
- (e) Administrator means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his authority to carry out his functions, or any other person who shall by operation of law be authorized to carry out such functions.
- (f) An article is a manufactured item: (1) Which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 710.4(d)(5); except that fluids and particles are not considered articles regardless of shape or design.
- (g) Byproduct means a chemical substance produced without separate commercial intent during the manufacture or processing of another chemical substance(s) or mixture(s).
- (h) Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that "chemical substance" does not include:
- (1) Any mixture,
- (2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide,
- (3) Tobacco or any tobacco product, but not including any derivative products,
- (4) Any source material, special nuclear material, or byproduct material,
- (5) Any pistol, firearm, revolver, shells, and cartridges, and
- (6) Any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.
- (i) Commerce means trade, traffic, transportation, or other commerce: (1) Between a place in a State and

any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce described in paragraph (i)(1) of this section.

- (j) Distribute in commerce and distribution in commerce when used to describe an action taken with respect to a chemical substance or mixture or article containing a substance or mixture, mean to sell or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.
- (k) EPA means the U.S. Environmental Protection Agency.
- (l) Importer means any person who imports any chemical substance or any chemical substance as part of a mixture or article into the customs territory of the U.S. and includes:
- (1) The person primarily liable for the payment of any duties on the merchandise, or
- (2) An authorized agent acting on his behalf (as defined in 19 CFR 1.11).
- (m) Impurity means a chemical substance which is unintentionally present with another chemical substance.
- (n) Intermediate means any chemical substance:
- (1) Which is intentionally removed from the equipment in which it is manufactured, and (2) which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s).

Note: The equipment in which it was manufactured includes the reaction vessel in which the chemical substance was manufactured and other equipment which is strictly ancillary to the reaction vessel, and any other equipment through which the chemical substance may flow during a continuous flow process, but does not include tanks or other vessels in which the chemical substance is stored after its manufacture.

- (o) Manufacture means to produce or manufacture in the United States or import into the customs territory of the United States.
- (p) Manufacture or import "for commercial purposes" means to manufacture or import:
- (1) For distribution in commerce, including for test marketing purposes, or
- (2) For use by the manufacturer, including for use as an intermediate.
- (q) Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that "mixture" does include:

- (1) Any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined and if, after the effective date or premanufacture notification requirements, none of the chemical substances comprising the combination is a new chemical substance, and
- (2) Hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water.
- (r) New chemical substance means any chemical substance which is not included in the inventory compiled and published under subsection 8(b) of the Act.
- (s) Person means any natural or juridicial person including any individual, corporation, partnership, or association, any State or political subdivision thereof, or any municipality, any interstate body and any department, agency, or instrumentality of the Federal Government.
- (t) Process means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.
- (u) Process for "commercial purposes" means to process (1) for distribution in commerce, including for test marketing purposes, or (2) for use as an intermediate.
- (v) Processor means any person who processes a chemical substance or mixture.
- (w) Site means a contiguous property unit. Property divided only by a public right-of-way shall be considered one site. There may be more than one manufacturing plant on a single site. For the purposes of imported chemical substances, the site shall be the business address of the importer.
- (x) Small manufacturer or importer means a manufacturer or importer whose total annual sales are less than \$5,000,000, based upon the manufacturer's or importer's latest complete fiscal year as of January 1, 1978, except that no manufacturer or importer is a "small manufacturer or importer" with respect to any chemical substance which such person manufactured at one site or imported in quantities greater than 100,000 pounds during calendar year 1977. In the case of a company which is owned or controlled by another company, total annual sales shall be based on the total annual sales of the owned or controlled company, the parent company, and all companies owned or controlled by the parent company taken together.

Note: The purpose of the exception to the definition is to ensure that manufacturing and importers report production volumes for all chemical substances which they manufactured at one site or imported in quantities equal to or greater than 100,000 pounds during calendar year 1977.

(y) Small quantities for purposes of scientific experimentation or analysis or chemical research on, or

analysis of, such substance or another substance, including any such research or analysis for the development of a product (hereinafter sometimes shortened to small quantities for research and development) means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed that (1) are no greater than reasonably necessary for such purposes and (2) after the publication of the revised inventory, are used by, or directly under the supervision of, a technically qualified individual(s).

Note: Any chemical substances manufactured, imported or processed in quantities less than 1,000 pounds annually shall be presumed to be manufactured, imported or processed for research and development purposes. No person may report for the inventory any chemical substance in such quantities unless that person can certify, that the substance was not manufactured, imported, or processed solely in small quantities for research and development, as defined in this section.

- (z) State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.
- (aa) Technically qualified individual means a person: (1) Who because of his education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under his supervision, (2) who is responsible for enforcing appropriated methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in paragraph (aa)(3) of this section may be delegated to another individual, or other individuals, as long as each meets the

criteria in paragraph (aa)(1) of this section.

- (bb) Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture or article in commerce.
- (cc) United States, when used in the geographic sense, means all of the States, territories, and possessions of the United States.
- (dd) Master Inventory File means EPA's comprehensive list of chemical substances which constitute the Chemical Substances Inventory compiled under section 8(b) of the Act. It includes substances reported under subpart A of this part and substances reported under part 720 of this chapter for which a Notice of Commencement of Manufacture or Import has been received under § 720.120 of this chapter.
- (ee) Nonisolated intermediate means any intermediate that is not intentionally removed from the equipment

in which it is manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

(ff) Site-limited means a chemical substance is manufactured and processed only within a site and is not distributed for commercial purposes as a substance or as part of a mixture or article outside the site. Imported substances are never site-limited.

[42 FR 64572, Dec. 23, 1977, as amended at 60 FR 31921, June 19, 1995]

- § 710.4 Scope of the inventory.
- (a) Chemical substances subject to these regulations. Only chemical substances which are manufactured, imported, or processed "for a commercial purpose," as defined in § 710.2, are subject to these regulations.
- (b) Naturally occurring chemical substances automatically included. Any chemical substance which is naturally occurring and:
- (1) Which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or
- (2) Which is extracted from air by any means, shall automatically be included in the inventory under the category "Naturally Occurring Chemical Substances." Examples of such substances are: raw agricultural commodities; water, air, natural gas, and crude oil; and rocks, ores, and minerals.
- (c) Substances excluded by definition or section 8(b) of TSCA. The following substances are excluded from the inventory:
- (1) Any substance which is not considered a "chemical substance" as provided in subsection 3(2)(B) of the Act and in the definition of "chemical substance" in § 710.2(h);
- (2) Any mixture as defined in § 710.2(q);

Note: A chemical substance that is manufactured as part of a mixture is subject to these reporting regulations. This exclusion applies only to the mixture and not to the chemical substances of which the mixture is comprised. The term "mixture" includes alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement.

- (3) Any chemical substance which is manufactured, imported, or processed solely in small quantities for research and development, as defined in § 710.2(y); and
- (4) Any chemical substance not manufactured, processed or imported for a commercial purpose since January 1, 1975.

(d) Chemical substances excluded from the inventory. The following chemical substances are excluded from the inventory. Although they are considered to be manufactured or processed for a commercial purpose for the purpose of section 8 of the Act, they are not manufactured or processed for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they may be a part.

Note: In addition, chemical substances excluded here will not be subject to premanufacture notification under section 5 of the Act.

- (1) Any impurity.
- (2) Any byproduct which has no commercial purpose.

Note: A byproduct which has commercial value only to municipal or private organizations who (i) burn it as a fuel, (ii) dispose of it as a waste, including in a landfill or for enriching soil, or (iii) extract component chemical substances which have commercial value, may be reported for the inventory, but will not be subject to premanufacturing notification under section 5 of the Act if not included.

- (3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.
- (4) Any chemical substance which results from a chemical reaction that occurs incidental to storage of another chemical substance, mixture, or article.
- (5) Any chemical substance which results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles such as adhesives, paints, miscellaneous cleansers or other housekeeping products, fuels and fuel additives, water softening and treatment agents, photographic, films, batteries, matches, and safety flares, and which is not itself manufactured for distribution in commerce or for use as an intermediate.
- (6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints; or other chemical substances formed during manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that may occur as described elsewhere in this § 710.4(d).
- (7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or de-foamer, dispersant, precipitation inhibitor, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended or (ii) a chemical substance, solely intended to impart a specific physicochemical characteristic, functions as intended.

(8) Chemical substances which are not intentionally removed from the equipment in which they were manufactured.

Note: See note to definition of "intermediate" at § 710.2(n) for explanation of "equipment in which it was manufactured."

[42 FR 64572, Dec. 23, 1977]

§ 710.25 Chemical substances for which information must be reported.

Any chemical substance which is in the Master Inventory File at the beginning of a reporting period described in § 710.33, unless the chemical substance is specifically excluded by § 710.26.

[51 FR 21447, June 12, 1986]

§ 710.26 Chemical substances for which information is not required.

The following categories of chemical substances are excluded from the reporting requirements of this subpart. However, a chemical substance described in paragraphs (a), (b), or (c) of this section is not excluded from the reporting requirements of this subpart if that substance is the subject of a rule proposed or promulgated under section 4, 5(a)(2), 5(b)(4), or 6 of the Act, or is the subject of an order issued under section 5(e) or 5(f) of the Act, or is the subject of relief that has been granted under a civil action under section 5(e) or 6(f) of the Act.

- (a) Inorganic chemical substances. Any chemical substance which does not contain carbon or contains carbon only in the form of carbonato [=CO3], cyano [-CN], cyanato [-OCN], isocyano [-NC], or isocyanato [-NCO] groups, or the chalcogen analogues of such groups.
- (b) Polymers. (1) Any chemical substance described with the word fragments "*polym*", "*alkyd", or "*oxylated" in the Chemical Abstracts Service Index or Preferred Nomenclature in the Chemical Substance Identities section of the 1985 edition of the Inventory or in the Master Inventory File, where the asterisk (*) indicates that any sets of characters may precede, or follow, the character string defined.
- (2) Any chemical substance which is identified in the 1985 edition of the Inventory or the Master Inventory File as siloxane and silicone, silsesquioxane, a protein (albumin, casein, gelatin, gluten, hemoglobin), an enzyme, a polysaccharide (starch, cellulose, gum), rubber, or lignin. This exclusion, however, does not apply to a chemical substance which has been hydrolyzed, depolymerized, or chemically modified to the extent that the final product is no longer polymeric in structure.
- (c) Microorganisms. Any combination of chemical substances that is a living organism, such as bacteria, eimeria, fungi, and yeasts. Any chemical substance produced from such a living organism is reportable unless otherwise excluded.

(d) Naturally occurring chemical substances. Any naturally occurring chemical substance, as described in § 710.4(b). The applicability of this exclusion is determined in each case by the specific activities of the person who manufactures the substance in question. Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person described in § 710.28 manufactures a chemical substance by means other than those described in § 710.4(b), the person must report regardless of whether the substance also could have been produced as described in § 710.4(b). Any chemical substance that is produced from such a naturally occurring chemical substance described in § 710.4(b) is reportable unless otherwise excluded.

[51 FR 21447, June 12, 1986]

§ 710.28 Persons who must report.

Except as provided in §§ 710.29 and 710.30, the following persons are subject to the requirements of this subpart. Persons must determine whether they must report under this § 710.28 for each chemical substance that they manufacture at an individual site.

- (a) Persons subject to initial reporting. Any person who manufactured for commercial purposes 10,000 pounds (4,540 kilograms) or more of a chemical substance described in § 710.25 at any single site owned or controlled by that person at any time during the person's latest complete corporate fiscal year before August 25, 1986.
- (b) Persons subject to recurring reporting. Any person who manufactured for commercial purposes 10,000 pounds (4,540 kilograms) or more of a chemical substance described in § 710.25 at any single site owned or controlled by that person at any time during the person's latest complete corporate fiscal year before August 25, 1990, or before August 25 at four-year intervals thereafter.
- (c) Special provisions for importers. For purposes of paragraphs (a) and (b) of this section, the site for a person who imports a chemical substance described in § 710.25 is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction. The import site may in some cases be the organization's headquarters in the U.S. (See also § 710.35(b).)

[51 FR 21447, June 12, 1986]

§ 710.29 Persons not subject to this subpart.

A person described in § 710.28 is not subject to the requirements of this subpart if that person qualifies as a small manufacturer as that term is defined in § 704.3 of this chapter. Notwithstanding this exclusion, a person who qualifies as a small manufacturer is subject to this subpart with respect to any chemical substance that is the subject of a rule proposed or promulgated under section 4, 5(b)(4), or 6 of the Act, or is the subject of an order in effect under section 5(e) of the Act, or is the subject of relief that has been granted under a civil action under section 5 or 7 of the Act.

[51 FR 21447, June 12, 1986]

§ 710.30 Activities for which reporting is not required.

A person described in § 710.28 is not subject to the requirements of this subpart with respect to any chemical substance described in § 710.25 that the person manufactured or imported under the following circumstances:

- (a) The person manufactured or imported the chemical substance described in § 710.25 solely in small quantities for research and development,
- (b) The person imported the chemical substance described in § 710.25 as part of an article,
- (c) The person manufactured the chemical substance described in § 710.25 in a manner described in § 720.30(g) or (h) of this chapter.

[51 FR 21447, June 12, 1986]

§ 710.32 Reporting information to EPA.

Any person who must report under this part must submit the information prescribed in this section for each chemical substance described in § 710.25 that the person manufactured for commercial purposes in an amount of 10,000 pounds (4,540 kilograms) or more at a single site during a corporate fiscal year described in § 710.28. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.). A respondent to this subpart must report information in writing or by magnetic media as prescribed in this section, to the extent that such information is known to or reasonably ascertainable by that person. A respondent to this subpart must report information that applies to the specific corporate fiscal year for which

the person is required to report.

- (a) Reporting in writing. Any person who chooses to report information to EPA in writing must do so by completing the reporting form available from EPA at the address set forth in § 710.39(b). The form must include all information prescribed in paragraph (c) of this section. Persons reporting in writing must submit a separate form for each site for which the person is required to report.
- (b) Reporting by magnetic media. Any person who chooses to report information to EPA by means of magnetic media must submit the information prescribed in paragraph (c) of this section. Magnetic media submitted in response to this subpart must meet EPA specifications, as described in the instruction booklet available from EPA at the address set forth in § 710.39(b).
- (c) Information to be reported. Persons reporting information under this subpart must report the following:

- (1) The name, company, address, city, State, Zip code, and telephone number of a person who will serve as technical contact for the respondent company, and will be able to answer questions about the information submitted by the company to EPA. Persons reporting by means of magnetic media must submit this information on the reporting form available from EPA at the address set forth in § 710.39.
- (2) A certification statement signed and dated by an authorized official of the respondent company. Persons reporting by means of magnetic media must submit this information on the reporting form available from EPA at the address set forth in § 710.39.
- (3) The specific chemical name and Chemical Abstracts Service (CAS) Registry Number of each chemical substance for which reporting is required under this subpart. A respondent to this subpart may use other chemical identification numbers in lieu of CAS Registry Numbers when a CAS Registry Number is not known to the respondent as provided in the instruction booklet identified in § 710.39(b), including EPA-designated Accession Numbers for confidential substances, EPA-assigned numbers for bona fide or Premanufacture Notification submissions, or Test Market Exemption Applications, or original Inventory form numbers.
- (4) The name, street address, city, State, and Zip code of each site at which 10,000 pounds (4,540 kilograms) or more of a chemical substance for which reporting is required under this subpart is manufactured or imported. (The site for a person who imports a chemical substance is the site of the operating unit within the person's organization which is directly responsible for importing the substance and which controls the import transaction, and may in some cases be the organization's headquarters office in the U.S.) A respondent to this subpart must include the appropriate Dun and Bradstreet Number for each plant site reported.
- (5) A statement for each substance for which information is being submitted indicating whether the substance is manufactured in the United States or imported into the United States.
- (6) A statement for each substance for which information is being submitted indicating whether the substance is site-limited.
- (7) The total volume (in pounds) of each subject chemical substance manufactured or imported at each site. This amount must be reported to two significant figures of accuracy provided that the reported figures are within ± 10 percent of the actual volume.

[55 FR 39587, Sept. 27, 1990, as amended at 60 FR 31921, June 19, 1995]

§ 710.33 When to report.

All information reported to EPA in response to the requirements of this subpart must be submitted during an applicable reporting period. The following reporting periods are prescribed for this subpart.

(a) Initial reporting period. The first reporting period is from August 25, 1986 to December 23, 1986. Any

person described in § 710.28(a) must report during this period for each chemical substance described in § 710.25 that the person manufactured during the corporate fiscal year described in § 710.28(a).

- (b) Recurring reporting periods. The first recurring reporting period is from August 25, 1990 to December 23, 1990. Subsequent reporting periods, except as provided in paragraph (c) of this section, are from August 25 to December 23 at 4-year intervals thereafter. Any person described in § 710.28(b) must report during the appropriate reporting period for each chemical substance described in § 710.25 that the person manufactured during the applicable corporate fiscal year described in § 710.28(b).
- (c) Reporting in 1998. The 1998 reporting period is from August 25, 1998 until January 31, 1999. Any person described in § 710.28(b) must report during this reporting period for each chemical substance described in § 710.25 that the person manufactured during the applicable corporate fiscal year described in § 710.28(b). This reporting period is applicable to 1998 reporting only.

[51 FR 21447, June 12, 1986: 51 FR 22521, June 20, 1986, as amended at 63 FR 71600, Dec. 29, 1998]

- § 710.35 Duplicative reporting.
- (a) With regard to section 8(a) rules. Any person subject to the requirements of this part who previously has complied with reporting requirements of a rule under section 8(a) of the Act by submitting the information described in § 710.32 for a chemical substance described in § 710.25 to EPA, and has done so within one year of the start of a reporting period described in § 710.33, is not required to report again on the manufacture of that substance at that site during that reporting period.
- (b) With regard to importers. This part requires that only one report be submitted on each import transaction involving a chemical substance described in § 710.25. When two or more persons are involved in a particular import transaction and each person meets the Agency's definition of "importer" as set forth in §§ 710.2(l) and 704.3 of this chapter, they may determine among themselves who should submit the required report; if no report is submitted as required under this part, EPA will hold each such person liable for failure to report.

[51 FR 21447, June 12, 1986, as amended at 60 FR 31921, June 19, 1995]

§ 710.37 Recordkeeping requirements.

Each person who is subject to the reporting requirements of this part must maintain records that document any information reported to EPA. For substances that are manufactured or imported at less than 10,000 pounds annually, volume records must be maintained as evidence to support a decision not to submit a report. Records relevant to reporting during a reporting period described in § 710.33 must be retained for a period of four years beginning with the effective date of that reporting period.

[51 FR 21447, June 12, 1986, as amended at 58 FR 34204, June 23, 1993; 60 FR 31921, June 19,

- § 710.38 Confidentiality.
- (a) Any person submitting information under this part may assert a business confidentiality claim for the information. The procedures for asserting confidentiality claims are described in the instruction booklet identified in § 710.39. Information claimed as confidential in accordance with this section and those instructions will be treated and disclosed in accordance with the procedures in part 2 of this chapter.
- (b) A person may assert a claim of confidentiality for the chemical identity of a specific chemical substance only if the identity of that substance is treated as confidential in the Master Inventory File as of the time the report is submitted for that substance under this part.
- (c) To assert a claim of confidentiality for the chemical identity of a specific chemical substance, the person must take the following steps:
- (1) The person must submit with the report detailed written answers to the following questions signed and dated by an authorized official.
- (i) What harmful effects to your competitive position, if any, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?
- (ii) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?
- (iii) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?
- (iv) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?
- (v) Is the fact that the chemical substance is being manufactured or imported for a commercial purpose available to the public, for example in technical journals, libraries, or State, local, or Federal agency public files?
- (vi) What measures have you taken to prevent undesired disclosure of the fact that this chemical substance is being manufactured or imported for a commercial purpose?
- (vii) To what extent has the fact that this chemical substance is manufactured or imported for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have

there been public disclosures or disclosures to competitors?

- (viii) Does this particular chemical substance leave the site of manufacture in any form, as product, effluent, emission, etc.? If so, what measures have you taken to guard against discovery of its identity?
- (ix) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the substance be identified by analysis of the product?
- (x) For what purpose do you manufacture or import the substance?
- (xi) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.
- (2) If any of the information contained in the answers to the questions is asserted to contain confidential business information, the person must mark that information as "trade secret," "confidential," or other appropriate designation.
- (d) If no claim of confidentiality accompanies information at the time it is submitted to EPA under this part or if substantiation required under paragraph (c) of this section is not submitted with the reporting form, EPA may make the information available to the public without further notice to the submitter.
- [51 FR 21447, June 12, 1986, as amended at 55 FR 39588, Sept. 27, 1990; 60 FR 31921, June 19, 1995]
- § 710.39 How do I submit the required information for the 1998 reporting cycle?
- (a) Use the proper EPA form. You must use the EPA form identified as "Form U" to submit written information in response to the requirements of this subpart. Copies of the Form U are available from EPA at the address set forth in paragraph (c) of this section, from the EPA Internet Home Page at http://www.epa.gov/opptintr/iur98, or via Fax-on-Demand by using a faxphone to call (202) 401-0527 and selecting item 5119.
- (b) Follow the reporting instructions. You should follow the detailed instructions for completing the reporting form and preparing a magnetic media report, which are given in the EPA publication entitled "Instructions for Reporting for Partial Updating of the TSCA Chemical Inventory Data Base," via the Internet or the TSCA Hotline.
- (c) Obtain the reporting package and copies of the form. EPA is mailing the reporting package to those companies that reported in 1994. Failure to receive a reporting package does not obviate or otherwise affect the requirement to submit a timely report. If you did not receive a reporting package, but are required to report, you may obtain a copy of the reporting package and the reporting form from EPA by submitting a request for this information as follows:

- (1) By phone. Call the EPA TSCA Hotline at (202) 554-1404, or TDD 202-554-0551.
- (2) By e-mail. Send an e-mail request for this information to the EPA TSCA Hotline at TSCA-Hotline@epamail.epa.gov.
- (3) By mail. Send a written request for this information to the following address: TSCA Hotline, Mail Code 7408, ATTN: Inventory Update Rule, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- (d) Submit the completed reports. You must submit your completed reporting form(s) and/or magnetic media to EPA at the following address: Document Control Officer, Mail Code 7407, ATTN: Inventory Update Rule, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

[63 FR 45953, Aug. 28, 1998]

[This data current as of the Federal Register dated July 9, 2001]

ATTACHMENT 3

Form U and Instructions (*EPA Form #7740-8*) Available electronically at http://www.epa.gov/opptintr/iur98/forms.htm.

ATTACHMENT 4

Methodology for Determination of Wage Rates

Determination of Wage Rates

Wage rates were developed from information published by the Bureau of Labor Statistics (BLS) and the chemical industry. As presented in Table 4-1, the managerial- and technical-level salaries used for the analysis are composites of the BLS average salaries for several occupation categories and levels. Weighting factors were applied to the average salaries for each of the occupation categories within the managerial and technical labor categories to develop the composite salary. The weighting factors are based on information provided by the chemical industry and chemical industry trade associations for the typical fraction of total reporting effort that is accounted for by each specific BLS occupation category (EPA, 1997a).

The 1993 composite annual salary estimates were adjusted to first-quarter 2000 dollars using the Employment Cost Index (ECI) for white-collar occupations in private industries. The three labor rates were each adjusted using separate categories. The clerical rate was adjusted using the Administrative Support, including Clerical Occupations data, the technical rate was adjusted using the Professional Specialty and Technical Occupations data, and the managerial rate was adjusted using the Executive, Administrative and Managerial Occupations data. The 2000 adjusted, composite salaries for the managerial, technical, and clerical labor categories were then multiplied by benefits and overhead factors to estimate 2000 loaded, annual salaries. Detailed benefits data for white-collar occupations in private, goods-producing industries were used to account for the additional cost of benefits for managerial, technical, and clerical labor. The overhead factor of 17 percent is based on information provided by the chemical industry and chemical industry trade associations. The loaded annual salary was then divided by 2,080 hours (i.e., the average annual number of hours worked per year by a full-time employee) to derive the loaded, hourly wage rates used in this analysis for each labor category.

Table 4-1. Loaded Hourly Wage Rates by Labor Category

Occupation (levels)	Average Salary (\$1993)	Weighting Factor	Comp. Salary ^a (\$1993)	ECI Ratio 3/00:6/93 ^b	Adjusted Salary (\$2000)	2000 Benefits (% Salary)	2000 Overhead (% Salary)	Loaded Annual Salary (\$2000)	Loaded Hourly Rate (\$2000)
Managerial									
Engineer (6-8)	\$93,981	10/17	\$55,283						
Attorney (4-6)	\$111,263	5/17	\$32,724						
Account (5-6)	\$73,528	2/17	\$8,650						
Composite		17/17	\$96,658	1.33	\$128,555	\$37.6	17.0	\$198,746	\$95.55
Technical									
Engineer (3-8)	\$74,802	5/6	\$62,335						
Account (3-6)	\$59,436	1/6	\$9,906						
Composite	_	6/6	\$72,241	1.23	\$88,856	\$37.4	17.0	\$137,194	\$65.96
Clerical									
Secretary (1-5)	\$28,850	1/1	\$28,850						
Composite	_	1/1	\$28,850	1.26	\$36,351	\$39.6	17.0	\$56,926	\$27.37

^a 1993 composite salaries were determined by multiplying average salaries by the weighting factor and summing across occupations.

Sources: U.S. Environmental Protection Agency. April 1997a. *Economic Analysis of the Final Rule to Add Certain Industry Groups to EPCRA Section 313*. Office of Pollution Prevention and Toxics, Regulatory Impacts Branch.

Bureau of Labor Statistics (BLS). 2000. Employment Cost Index. <www.bls.gov>. As obtained April 28, 2000.

^b The ECI ratio measures the change in wages and salaries between June 1993 and March 2000.

ATTACHMENT 5

Display Related to OMB Control #2070-0070 -Listing of Related Regulations in 40 CFR Part 9.1

Display Related to OMB Control #2070-0057 - Listings of Related Regulations in 40 CFR 9.1

As of May 10, 1993, the OMB approval numbers for EPA regulations in Chapter I of Title 40 of the Code of Federal Regulations (CFR) appear in a listing in 40 CFR 9.1 (58 FR 27472). This listing fulfills the display requirements in section 3507(f) of the Paperwork Reduction Act (PRA) for EPA regulations. The listing at 40 CFR 9.1 displays this OMB Control number for the following regulations:

Program Title	40 CFR citation
Inventory Reporting Regulations	Part 710

ATTACHMENT 6

Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports; Request for Comment on Renewal of Information Collection Activities (66 FR 17704, April 3, 2001).

Available electronically at http://www.epa.gov/fedrgstr/EPA-TOX/2001/April/Day-03/t8134.htm

ATTACHMENT 7

Comments Received in Response to April 3, 2001 Notice and Request for Comment (66 FR 17704)